(26)

No. 03-388

IN THE

Supreme Court of the United States

DENNIS BATES, ET AL.,
Petitioners,
v.

DOW AGROSCIENCES LLC,
Respondent.

On Writ of Certiorari to the United States Court of Appeals for the Fifth Circuit

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STATEMENT PURSUANT TO RULE 29.6

Petitioners' 29.6 Statement was set forth at page iii of petitioners' opening brief, and there are no amendments to that Statement.

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For more than a century until the mid-1990s, courts routinely recognized the rights of farmers to bring state-law claims for crop damage caused by unsafe pesticides, either because the product itself was defectively designed or manufactured, or because its label's use instructions were inadequate. Congress did not intend to affect those pre-existing remedies in the 1972 FIFRA amendments. Instead, it expressly retained a robust role for States to regulate the "sale or use" of pesticides, § 136v(a), and to approve new uses for special local needs, § 136v(c). The scope of preemption in § 136v(b) must be read in light of Congress's preservation of this critical and expansive state regulatory role.

The farmers who are petitioners here suffered substantial crop damage in the fields where they used Dow's Strongarm product; indeed, some petitioners did not use Strongarm in certain of their fields, where they experienced record crop production. Unlike other farmers who were prepared to accept pennies on the dollar in mediation for Dow's broken promises to remedy harms it had caused, petitioners had every right to bring state damages claims for fraud, strict liability, negligence, and breach of warranty. The Fifth Circuit erroneously held all of those claims preempted even though they (1) are based on the inefficacy of Strongarm – which EPA concededly does not review when registering a pesticide; (2) are based on state requirements that simply parallel FIFRA's misbranding requirements; and (3) do not impose labeling requirements different from or in addition to those imposed by FIFRA.

Even assuming FIFRA preempts claims challenging the label's use instructions, however, the Fifth Circuit erred, for example, in dismissing the farmers' defective design and manufacturing claims inasmuch as they challenge the safety of the Strongarm product itself (even apart from its false and misleading label), and the claims based on post-sale, off-label misrepresentations. Dow concedes that defective design, manufacturing, testing, and post-sale claims are generally not preempted. Those concessions compel remand. Dow nonetheless would give § 136v(b) such a broad scope as to denude

§ 136v(a) of practical effect: any time a manufacturer is "induced" to change the label in response to liability, damages remedies would be preempted. In *Medtronic* and *Cipollone*, this Court rejected similarly overbroad interpretations of preemption provisions that were broader in scope than § 136v(b) and did not expressly authorize States to regulate "sale or use" of products. As in *Medtronic*, which this Court also reviewed on the pleadings, the Court should reject Dow's preemption theories and remand for factual development and trial.

I. STATE-LAW DAMAGES CLAIMS ARE NOT PREEMPTED BY FIFRA

Congress did not intend for § 136v(b) to be an all-encompassing preemption provision. Dow focuses myopically on the word "requirements" in § 136v(b), but largely ignores the multiple ways in which § 136v(a) and (c) expressly permit States to regulate pesticides in ways that directly and indirectly induce a manufacturer to change its EPA-approved label. Dow thus disregards the fundamental principle that "[s]tatutory construction is a holistic endeavor." *Koons Buick Pontiac GMC, Inc. v. Nigh*, 125 S. Ct. 460, 466 (2004) (internal quotation marks omitted).

A. Section 136v(b) Evinces No Intent To Preempt Damages Claims Inducing A Label Change

The most logical way to read § 136v(b), in light of the text, structure, and history of the provision, is that Congress intended to preempt only state positive-law requirements that directly force a manufacturer to change a label. That construction is the most consistent with the long history of farmers bringing claims against manufacturers for damage and the absence of any indication that Congress intended to affect those remedies.

In *Wisconsin Public Intervenor v. Mortier*, 501 U.S. 597, 614 (1991), this Court explained that FIFRA did not occupy the field of pesticide regulation and that FIFRA must be interpreted in light of the presumption *against* preemption: the "specific grant of authority in § 136v(a) consequently does not serve to hand back to the States powers that the statute

had impliedly usurped. Rather, it acts to ensure that the States could continue to regulate use and sales even where, such as with regard to the *banning of mislabeled products, a narrow pre-emptive overlap might occur.*" *Id.* (emphasis added). Accordingly, the labeling uniformity sought in § 136v(b) is profoundly tempered by a State's express authority in § 136v(a) and (c) to regulate pesticide sale or use within its borders and to impose locality-specific requirements. That authority is not preempted even when it might induce a label change, because EPA has the final say on labeling, thereby ensuring uniformity.

Indeed, EPA regulations permit States to require that a pesticide be distributed with a supplemental label stating its "restricted use" within the State, so that state sale and use regulations are not undermined by lack of notice to consumers. *See* 40 C.F.R. § 162.153(e)(5) (States have authority directly to "require supplemental labeling for the product or use containing additional appropriate precautions, and a statement that the product or use is for restricted use within that State," even though FIFRA would not require the pesticide to be labeled for restricted use). That is not materially different from what Dow was supposedly "induced" to do by the farmers' reports of Strongarm's inefficacy: add a supplemental label for distribution only in Texas and two adjoining States providing (among other things) that Strongarm should not be used in soils of 7.2 pH or greater. Given the substantial authority for States to regulate pesticides – the result of which may be directly to require a manufacturer to change its label – damages claims based on use of a product that might *indirectly* induce a manufacturer's voluntary label change are not preempted.

Although the preemption provision in *Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996), is quite similar to the wording of § 136v(b) here – and five Justices held that *none* of the Lohrs' claims was preempted – the case for non-preemption is even stronger here. The Medical Device Amendments ("MDA") did not contain an express provision conferring broad authority on States to regulate the "sale or use" of medical devices. Rather, the Food and Drug Administration ("FDA") had regulatory authority to determine when certain more stringent state rules would not be preempted. In § 136v(a), however, *Congress* concluded that States themselves have broad authority to regulate pesticides more stringently than federal law in ways that invariably will directly and indirectly affect labels, and a State need not first get EPA's permission to do so. It is therefore inconsistent with FIFRA's statutory structure to read the word "requirements" in § 136v(b) as a sweeping prohibition on common-law claims; *Medtronic*'s majority view that under the MDA "requirements" includes damages claims does not control here.

B. Dow's Reliance On Legislative History Is Misplaced

Nothing in the legislative history suggests any intent to preempt damage actions. Indeed, it confirms that § 136v(b) is addressed almost exclusively to the authority of state legislatures and pesticide agencies, not to the availability of state-law remedies. *See* U.S. Amicus Br. at 18-31, *Etcheverry v. Tri-Ag Serv., Inc.*, No. S072524 (Cal. filed Mar. 23, 1999).[1] The absence of any discussion of eliminating state damages remedies stands in sharp contrast to the voluminous testimony on the harms caused by pesticides and debates over how far States should be permitted directly to regulate the pesticide industry. *See id.*; Pet. Br. 26; Peanut Growers Br. 19 & n.38, 20-30. No industry witness or other party expressed any concern that damages actions created uniformity problems, but they did complain about the types of state labeling requirements – formatting, coloring, wording – that had sometimes precluded a national label. *Id.* at 24-25. That history confirms that § 136v does not speak to common-law damages actions, but only state positive law.[2]

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[1] To the extent the legislative history refers to tort liability at all (and it does so only briefly), witnesses and members of Congress assumed it would remain unaffected by the 1972 FIFRA amendments. *See* Western Peanut Growers Ass'n et al. *Amicus* Br. 14-15 & nn.30-31.

[2] Dow relies (at 29 & n.19) on two references in the House report to state labeling being "completely preempted," H.R. Rep. No. 92-511, at 1-2, 16 (1971), but those references are inconsistent with the broad non-

Dow repeatedly (at 4, 29-30, 39-40) invokes Congress's rejection of a "citizen suit" provision, but history here validates the farmers' position. Senate Commerce Committee amendments proposed a "citizen suit" provision that explicitly left undisturbed pre-existing common-law remedies. The proposal permitted only "injunctive relief" against the EPA Administrator for failure "to perform an act or duty under this Act which is not discretionary" and against any "person" (including the United States or a State) "alleged to be in violation of" certain requirements in the Act. S. Rep. No. 92-970, at 4 (1972). The plain intent of the proposal, therefore, was to empower private attorneys general to ensure that FIFRA was enforced; it was not geared in any way to the kinds of private damages remedies for persons harmed by pesticides. To avoid any ambiguity about including a provision for injunctive relief without a corresponding damages remedy, however, the proposal expressly saved common-law damages actions: "Nothing in this section shall restrict any right which any person (or class of persons) may have under any other statute *or under common law* to seek enforcement of any regulation or order *or to seek any other relief.*" *Id.* at 5 (emphases added).

Congress received criticism of that proposal, not because it explicitly saved common-law suits from preemption, but because it authorized suits against the government for failure to act. Accordingly, the Senate Agriculture Committee proposed an amendment to remove authorization for citizen suits against the EPA Administrator. *See* S. Rep. No. 92-838, Pt. II, at 40 (1972). Importantly, and contrary to Dow's misleading description, the Agriculture Committee obviously perceived that a savings clause was otherwise unnecessary – because no other provision of FIFRA preempted state-law

preemption provisions of § 136v(a) and (c) that Congress ultimately adopted. The House report commented on a bill that conferred limited authority on States to regulate only one class of pesticides, those that FIFRA required to be designated for restricted use. As enacted, however, § 136v went much farther. *See* Peanut Growers Br. 26-28 (floor debates addressed concern that bill would gut state use laws stricter than FIFRA).

claims. Rather, its objection to the Commerce Committee proposal was that "courts should not be further burdened with suits by citizens who disagree with the manner in which the President is executing the laws." *Id.* at 39. When the Conference Committee deleted that provision in its entirety, its cursory explanation was that it had "deleted" a provision conferring "[a]uthority for certain types of citizen suits against the Administrator." H.R. Conf. Rep. No. 92-1540, at 34 (1972). There was no mention of any intent to affect common-law remedies. Without the citizen suit provision, those remedies were not otherwise perceived to be threatened by FIFRA. Seen in its proper light, this proposal supports the conclusion that Congress had no intent to preempt damages remedies.[3]

II. PETITIONERS' CLAIMS ARE OUTSIDE THE SCOPE OF § 136v(b) PREEMPTION

A. Efficacy Claims Are Not Preempted

Both parties and the government now agree that "EPA does not routinely scrutinize product efficacy in the initial registration process." Dow Br. 8; Gov't Br. 21 ("EPA has generally waived such requirements and typically does not conduct independent product efficacy evaluations.") (citing PR 96-4 (JA 228-35)). Dow and the government also concede that EPA did *not* base its conditional registration of Strongarm on any assessment of whether Strongarm harms peanut crops. Indeed, while Dow asserted in its opposition to certiorari that EPA in fact had assessed target-crop phytotoxicity, its merits brief is now silent on that issue. *See* Pet. Br. 33-35 & n.23 (rebutting those claims). Although Dow contends (at 10) that it submitted efficacy data that "reflect[] . . . target-crop phytotoxicity," it does not claim EPA reviewed them in registering

[3] Dow misconstrues commentary that the citizen-suit provision would "interfere with the orderly administration of the law" by omitting the preceding part of the quoted sentence, which addresses this concern to "professional litigants," and not persons injured by pesticides. S. Rep. No. 92-838, Pt. II, at 39 (criticizing that "costs of litigation [would] be awarded to any party whenever the court deemed appropriate without regard to whether such party prevailed in the suit").

Strongarm, and Dow does not even mention those data in its legal arguments as a basis for preemption.[4]

Notwithstanding EPA's non-consideration of efficacy, Dow claims (at 32-33) that § 136v(b) preemption is based only on requirements imposed by "FIFRA itself" and is unaffected by whether EPA assesses efficacy claims before granting a pesticide registration. In 1978, however, Congress amended "FIFRA itself" to *remove* the requirement that a pesticide's efficacy claims pass EPA muster as a precondition to registration. *See* Pet. Br. 7 (discussing § 136a(c)(5)). In any case, the phrase "under this subchapter" in § 136v(b) can, as even Dow recognizes (at 35), easily be "construed as referring to both FIFRA and its implementing regulations." *See* § 136w(a)(1) (EPA "may prescribe regulations to carry out the provisions of this subchapter"). The government also concedes as much.[5] Thus, FIFRA's removal of an efficacy review requirement, coupled with EPA's waiver, means that common-law claims challenging a pesticide's efficacy do not impose labeling "requirements" within § 136v(b)'s preemptive ambit. Such claims likewise raise no implied preemption concerns by posing an obstacle to accomplishment of Congress's aim of removing the burden on EPA to examine efficacy claims prior to registering a pesticide.

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[4] To the extent Dow suggests it can control the scope of preemption by submitting un-required data that EPA does not review, that suggestion should be rejected out of hand. In any case, a data submission requirement cannot be viewed as preemptive under FIFRA. The States necessarily have authority to require data submissions to fulfill their role in regulating pesticides under § 136v. *See, e.g.*, § 136a(c)(5) (last sentence) ("If a pesticide is found to be efficacious by any State under section 136v(c) of this title, a presumption is established that [EPA] shall waive data requirements pertaining to efficacy for use of the pesticide in such State."); § 136w-1 ("For the purposes of this subchapter, a State shall have primary enforcement responsibility for pesticide use violations").

[5] *See* Gov't Br. 4-5 ("Section 136v(a) recognizes that, as a general matter, States retain their historic authority to regulate pesticide sale or use, provided that a State does not permit a sale or use that FIFRA, *or EPA's implementing regulations*, prohibit") (emphasis added).

Moreover, EPA's authority to take corrective action *after* a pesticide has caused harm is no substitute for its failure to require accurate efficacy claims as a prerequisite to a pesticide's entry into the marketplace. *Medtronic* makes clear that an agency's statutorily authorized decision not to assess a product's efficacy before permitting it on the market means a state damages action is not in addition to or different from any relevant federal efficacy requirement. *See* Pet. Br. 33, 36. In *Medtronic*, FDA did not require the pacemaker it approved to take any particular form with respect to efficacy and safety, only that it be substantially equivalent to the design of a device already on the market. *See* 518 U.S. at 493-94. That process, like the EPA's here, "provide[d] little protection to the public" because the pacemaker was never "formally reviewed under the [MDA] for safety or efficacy." *Id.* at 493 (internal quotation marks omitted). This Court unanimously deemed irrelevant to preemption that the pacemaker (like Strongarm) had a continuing duty to satisfy statutory misbranding requirements. *Id.*

Dow attempts (at 33-34) to distinguish *Medtronic* on the erroneous ground that preemption rested on whether the agency itself had promulgated a preemptive requirement. But Dow overstates the proposition, for the Court said only that preemption would occur as a result of an agency-promulgated requirement "in most cases" – not all cases. 518 U.S. at 496. Indeed, the Court's analysis of the substantial-equivalence process (which Dow's argument ignores) focused not on whether the *agency* had acted to impose a requirement, but rather on the substantial-equivalence process and standards in the *statute* enacted by Congress. *See id.* at 492-93. And the Court specifically rejected the argument that FDA's action approving the pacemaker, along with the agency's continuing authority "to exclude the device from the market if its design is changed," constituted a preemptive requirement. *Id.* at 492. Similarly, here EPA approved Strongarm with no "requirement" (statutory or otherwise) that its efficacy claims be accurate as a precondition of registration.

Dow's reliance (at 34-35) on Congress's failure in 1978 substantively to amend § 136v(b) while inserting a technical change to that provision is similarly misplaced. Once Congress removed the "requirement" that a pesticide be shown to be efficacious before it can be marketed, there was no longer any basis (assuming there ever had been) in finding efficacy as a preemptive requirement "under this subchapter." § 136v(b). Nor can anything be read into congressional inaction after certain lower court decisions in the mid-1990s found preemption after *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504 (1992). First, EPA's PR 96-4 explained that those courts had wrongly assumed that EPA actually reviewed efficacy claims as a prerequisite to registration; thus, Congress's inaction reflects agreement with PR 96-4. *See* Pet. Br. 32 & n.21. In any case, the congressional inaction "argument deserves little weight in the interpretive process," especially "when, as here, Congress has not comprehensively revised a statutory scheme but has made only isolated amendments." *Alexander v. Sandoval*, 532 U.S. 275, 292 (2001) (alterations and internal quotation marks omitted).[6]

Finally, there is no merit to Dow's claim (at 35-36) that, in light of EPA's efficacy waiver, a damages suit would impose a state requirement "in addition to" a federal requirement. States plainly are permitted to make efficacy determinations in deciding whether to ban or restrict the sale or use of a pesticide under § 136v(a), and those evaluations may involve analysis of pesticide label claims and an assessment that they are false and thus misbranded. *See Mortier*, 501 U.S. at 614. Under Dow's reading of "in addition to," such state actions would be preempted, a result plainly inconsistent with congressional intent. In *Medtronic*, this Court rejected the very same argument made by the manufacturer. *See supra* p. 8; Pet. Medtronic Br. at 44-46, Nos. 95-754 & 95-886 (U.S. filed Mar. 1, 1996). Indeed, Congress explained the efficacy waiver precisely in terms that allowed EPA to consider the effect of market forces and private lawsuits in policing industry's sale of ineffective products. *See* Pet. Br. 31.

[6] Moreover, EPA expressly based its efficacy waiver on the availability of damages suits to remedy those harmed by ineffective pesticides. *See* Pet. Br. 31. Although the government argues (at 23 n.11) that EPA's statement is consistent with some claims not being label-related, such as design or manufacturing defect claims, EPA was addressing only the failure-to-warn claims that all three of the cases cited in PR 96-4 found preempted. *See* JA 231-32. In addition, although the government claims (at 20) that it reexamined its position on these issues after the California Supreme Court issued its ruling in *Etcheverry*, it does not dispute that that court based its decision on the erroneous assumption that EPA's efficacy waiver did *not* include target-crop phytotoxicity. *See* Pet. Br. 32 n.20; *cf.* Gov't Br. 4, 21 (agreeing that EPA's efficacy waiver *does* include target-crop phytotoxicity). The government therefore offers no principled basis for its preemption flip-flop.

B. The Farmers' Claims Are Consistent With FIFRA's Misbranding Requirements

Because the farmers' claims can be tried to a jury in a manner consistent with FIFRA's misbranding prohibition, they do not impose any "requirements for labeling or packaging in addition to or different from those required under [FIFRA]." § 136v(b). All nine Justices in *Medtronic* reached the same result under the similarly worded preemption clause in the MDA. *See* Pet. Br. 37-39. The Court found a remand for trial appropriate where (as here) the "precise contours of [plaintiffs'] theory of recovery have not yet been defined" because the "pre-emption issue was decided on the basis of the pleadings." 518 U.S. at 495.

1. *Medtronic*'s unanimous holding that parallel state requirements are not preempted is controlling here. Dow acknowledges (at 40 n.29) *Medtronic*'s conclusion "that a state-law suit could proceed provided that it were squarely based on a violation of a federal requirement under the MDA." It claims (*id.*), however, that "the assumption was that a state-tort suit would allege a violation of a highly specific federal regulation that was applicable to the particular device in question" and would therefore not be preempted; whereas a state requirement parallel to a "general" federal requirement would be preempted. There is no support for Dow's reading. The Court characterized the federal requirements that would not preempt parallel state law as "*general* rules regulating manu-

facturing practices and labeling." 518 U.S. at 492 (emphasis added). The misbranding provision here likewise provides generally that the product is misbranded if it does not "contain directions for use which are necessary for effecting the purpose for which the product is intended." § 136(q)(1)(F). As the Solicitor General told the Court in *Medtronic*, state juries could be instructed "consistent with the federal labeling requirements" to determine whether the label was "false or misleading" or contains "adequate directions for use." U.S. Amicus Br. at 27-28, Nos. 95-754 & 95-886 (U.S. filed Mar. 13, 1996).[7] FIFRA compels the same result.

Although the government now supports preemption of parallel state requirements under FIFRA, it erroneously contends (at 26 n.13) that *Medtronic* based its parallel-requirements holding on the ground that state requirements in conflict with a device-specific federal requirement are preempted. But the *Medtronic* majority rooted its holding on the fact that parallel state "damages remed[ies] were not 'different from, or in addition to,'" federal requirements. 518 U.S. at 495 (quoting 21 U.S.C. § 360k(a)(1)). To be sure, as the government notes, the Court added that its textual analysis was informed by FDA regulations, but the cited regulations provided that *even a device-specific FDA regulation* "'does not preempt State or local requirements that are equal to, or substantially identical to, requirements imposed by or under the act.'" *Id.* at 496-97 (quoting 21 C.F.R. § 808.1(d)(2) (1995)). Thus, a parallel

[7] Dow (at 42) and the government (at 25) rely on a discussion in *Geier v. American Honda Motor Co.*, 529 U.S. 861, 871 (2000), of the possibility that juries can "reach different decisions on similar facts." There, however, the Court addressed a preemption provision prohibiting state requirements that are not "identical to" federal ones, which is quite unlike the preemption provision at issue here (and in *Medtronic*). *Id.* at 867. As Justice Breyer's opinion for the Court explained, that language meant preemption even of state standards "that might stand in harmony with federal law." *Id.* at 871; *see id.* at 868 (explaining that preemption would attach to "nonidentical state standards . . . even if the federal standard merely established a minimum standard").

state-law misbranding claim escaped preemption only because it was not "different from, or in addition to," federal law.

Dow's implausible argument against parallel state-law requirements is rooted in its contention that FIFRA makes EPA the sole decisionmaker on whether a pesticide is misbranded. That claim lacks any textual grounding in § 136v(b)'s preemption language or § 136(q)'s misbranding requirements. Indeed, all nine Justices in *Medtronic* rejected an indistinguishable claim without discussion, because the medical device manufacturer had (like Dow here) argued at some length against parallel state-law requirements by claiming that "[t]he inability of courts to ensure consistency in practice would create an irregular pattern of liability exposure for device manufacturers, undermining the congressional intent to impose uniform requirements." Cross-Respondent Medtronic Br. at 44, Nos. 95-754 & 95-886 (U.S. filed Mar. 29, 1996); *see id.* at 44-46.[8]

Dow cites (at 38-39) FIFRA's enforcement provisions as support for a supposedly exclusive role by EPA, but FDA also had similar enforcement authority under the MDA. That fact was not taken to preempt parallel state laws, as the Court subsequently reaffirmed in *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341, 353 (2001) ("*Medtronic* can be read to allow certain state-law causes of actions that parallel federal safety requirements"). Dow's reliance (at 38-39) on *Buckman* is inapposite, for the claim held preempted there was for fraud on the agency alleging that the "but-for" cause of plaintiff's injuries was fraudulent representations made to FDA, without which the medical device would not have been allowed on the market. Here, however, the farmers' claims are based on fraudulent statements made directly to them by

[8] Notably, the decision unanimously reversed on this point in *Medtronic* had relied on a FIFRA case holding that allowing a lay jury to pass on negligence and failure-to-warn claims that paralleled FIFRA's labeling standards would usurp EPA's role. *See Lohr v. Medtronic, Inc.*, 56 F.3d 1335, 1343 (11th Cir. 1995) (citing *Papas v. Upjohn Co.*, 985 F.2d 516 (11th Cir. 1993)).

the manufacturer, as well as design and manufacturing defects. *See* 531 U.S. at 352 ("[I]t is clear that the *Medtronic* claims arose from the manufacturer's alleged failure to use reasonable care in the production of the product, not solely from the violation of FDCA requirements.").

2. Dow's theory of uniformity also contravenes the text and structure of FIFRA, which gives substantial power to the States to interpret and enforce its provisions. *See Mortier*, 501 U.S. at 615; § 136t(b). Adoption of Dow's theory would require the incongruous conclusion that § 136v(b) preempts Texas's pesticide agency from restricting the use of Strongarm where soil pH was 7.2 or greater, because that would conflict with the original label's claims that it was appropriate for use in all areas where peanuts are grown. Indeed, under § 136v(a), a State may apply a more stringent misbranding standard under state law and ban a pesticide that is not mislabeled under FIFRA. It follows *a fortiori* that a state standard that is parallel to federal requirements cannot be preempted.[9] Thus, a jury applying standards of state law parallel to FIFRA's misbranding requirements would not impose any requirement that § 136v(b) preempts.

In addition, § 136v(c) allows a State to register pesticides "for additional uses of federally registered pesticides formulated for distribution and use within that State to meet special local needs in accord with the purposes of [FIFRA]." § 136v(c)(1). EPA requires a State registering a new product to require that its "labeling meet[] all applicable criteria of [40 C.F.R.] § 156.10." 40 C.F.R. § 162.153(e)(2). Rule 156.10, in turn, proscribes "false or misleading statement[s]," including those concerning "the effectiveness of the . . . pesticide."

[9] State misbranding statutes are often premised on FIFRA. *See, e.g.*, Tex. Agric. Code Ann. § 76.023 ("pesticide or device is misbranded if: (1) it is subject to registration under FIFRA and it does not fully comply with the labeling requirements of [EPA]"); N.Y. Envtl. Conserv. Law § 33-0101(32)(i) (pesticide is misbranded if its labeling "fails to conform to the labeling requirements of [FIFRA]"). *Cf.* EPA, FIFRA Statute, Regulations & Enforcement ("State laws generally mirror FIFRA."), *at* http://www.epa.gov/compliance/civil/programs/fifra/fifraenfstatreq.html.

Id. § 156.10(a)(5)(ii); *see also id.* § 156.10(*i*)(1)(i) ("directions [for use] must be adequate to protect the public from fraud and from personal injury and to prevent unreasonable adverse effects on the environment"). A State therefore is *required* in registering a pesticide for a state-specific use to mandate labeling in compliance with FIFRA – including FIFRA's own misbranding requirements. Dow thus cannot be correct that a court is precluded from interpreting those very same requirements, much less lack the power to apply a parallel state-law standard to judging remedial claims.[10] Dow's contention that FIFRA requires all misbranding determinations to be made by EPA cannot withstand scrutiny, and Dow fails to explain why having the same standard decided in the context of a private lawsuit would impose a requirement "in addition to or different from" parallel FIFRA misbranding requirements. *Cf. California v. Zook*, 336 U.S. 725, 736 (1949) (no preemption where the "case concerns only the state's mechanisms for enforcing a statute identical with that of the federal government").[11]

[10] *See also* § 136g(a)(1)-(2) (empowering "any State duly designated by [EPA]" to inspect samples of any pesticides and "containers or labeling for such pesticides," so long as the State "include[es] a statement as to whether a violation of the law is suspected").

[11] Dow's reliance (at 41) on *San Diego Building Trades Council v. Garmon*, 359 U.S. 236 (1959), is misplaced. That case concerned an area of labor law (union picketing) in which the Court found Congress to have established federal preemption through the exclusive authority vested in the National Labor Relations Board. *See Brown v. Hotel & Rest. Employees*, 468 U.S. 491, 502 (1984); *see also English v. General Elec. Co.*, 496 U.S. 72, 86-87 n.8 (1990). In *Mortier*, however, this Court expressly rejected that same approach to FIFRA. *See* 501 U.S. at 605-07; Pet. Br. 21. In view of the substantial authority in § 136v for States to regulate mislabeled products, no such implied preemption (much less a presumption of it) could be applicable here. *Chicago & North Western Transportation Co. v. Kalo Brick & Tile Co.*, 450 U.S. 311, 321 (1981), rested on the ground that pervasive federal regulation giving the Interstate Commerce Commission "exclusive and plenary" jurisdiction to regulate rail-service abandonments was "critical to the congressional scheme," but here, again, FIFRA expressly preserves substantial state authority to ban

C. The Farmers' Claims Do Not Add "Different" or "Additional" Requirements Under § 136v(b)

Even if this Court rejects the foregoing arguments on efficacy and misbranding, it must still reverse because the claims asserted by the farmers would not impose requirements "different from or in addition to" FIFRA requirements. Importantly, this case was dismissed before discovery had occurred and the farmers' claims could be fleshed out with evidence on the feasibility of alternate, safer formulations of Dow's product that would not burn peanut roots in high pH soils. Accordingly, the evidence after discovery and trial need not be based on a failure-to-warn theory. Following *Cipollone*, *Medtronic* re-emphasized that the relevant "requirements" for preemption were the legal duties underlying each state-law claim. *See* Pet. Br. 40-48. Because the legal duties flowing from the farmers' claims would not impose "labeling requirements," their claims are not preempted.[12] Dow repeat-

mislabeled products, which necessarily entails the authority to interpret federal misbranding standards.

[12] Notably, the government takes no position on whether the farmers' individual claims survive preemption. Instead, it claims the farmers "did not challenge the court of appeals' ruling that petitioners' claims are 'label-related' in the sense that 'a judgement [*sic*] against [Dow] would induce it to alter its product label.'" Gov't Br. 27 (quoting Pet. App. 15a). The government's plea, which seeks to dodge its contradictory positions taken just five years ago, simply ignores the question on which certiorari was granted: "Which, if any, state-law crop damage claims are preempted by [FIFRA]." Pet. i. It also overlooks the statement (Pet. 28) that this case "includes the vast array of claims that would normally be brought in a crop injury case: breach of warranty, fraud, violations of state consumer protection laws, and strict liability based on defective design." Second, the court below did not merely announce a test and then remand for the district court to apply it, but instead analyzed the claims and dismissed them all, so its full judgment is before this Court. Third, *Cipollone* and *Medtronic* each engaged in an analysis of the state-law claims presented. Fourth, the farmers' discussion of the varying appellate court tests explained why certiorari was warranted, but never suggested the farmers were not challenging the Fifth Circuit's analysis of their claims. Finally, Dow itself does not make this argument, thus acknowledging that the farmers' claims are properly before the Court.

edly acknowledges that the farmers' claims in theory should not be preempted, but argues lamely that they should be foreclosed from an opportunity to prove their claims. Dow's use of the declaratory judgment mechanism should not be allowed to deny the farmers their day in court.

1. *Strict Liability.* Dow relies on its broad inducement theory and ignores that a trial could show that Strongarm's product design was defective *even assuming* its warnings were adequate. As our opening brief explains (at 40-42, 47-48), under Texas law and the Restatement of Torts, warnings do not negate a failure to provide a reasonably safe design.[13]

Dow concedes (at 43) that defective design theories are not preempted, but nonetheless asserts that, because Dow supposedly could have marketed Strongarm in a reasonably safe manner with a different label, all such claims necessarily reduce to a failure to warn. But the farmers allege that Dow could have designed the product in a safer manner to comport with the use claims made on its label. Indeed, a jury verdict based on such evidence plainly would not be rooted in a failure to warn, but rather in Dow's failure to design Strongarm in a reasonably safe manner. A properly designed herbicide could thus retain the 2000 label's use instruction. *See Restatement (Third) of Torts: Product Liability* § 2 (1998) (explaining three independent theories of defect based on "manufacturing," "design," or "inadequate instructions or warnings"); *Turner v. General Motors Corp.*, 584 S.W.2d 844, 847 (Tex. 1979) (same). This Court should reject Dow's broad theory, which would allow a manufacturer to market an unsafe pesticide that it reasonably could have designed in a safer manner with a label that far exceeded what the product could deliver, and then claim immunity from damages under FIFRA because it could have used different label instructions.[14]

[13] The lower courts were in such a rush to dismiss this case that they did so despite the fact that Dow's motion for summary judgment (C.A. Rec. 262-325) did not even mention the farmers' strict-liability claims.

[14] Dow invokes (at 30) cases on the broader question whether damages claims can ever be FIFRA "requirements." But the same decisions have

Dow wrongly claims the farmers defaulted procedurally by not introducing "evidence of a safer, feasible alternative design" or "evidence of a manufacturing or formulation defect." Br. 44; *see also* Texas Chemical Council Br. 5-10. Neither lower court addressed that argument, and this Court should not do so in the first instance. Dow never raised its evidentiary theory in the district court because its summary judgment motion was based solely on preemption (plus a legal argument on limitation of remedies) – not on the merits of the

consistently *refused* to preempt design and manufacturing defect claims not premised on a failure to warn (even though some courts have overreached by applying an "inducement" theory similar to the court of appeals here). *See, e.g.*, *Worm v. American Cyanamid Co.*, 970 F.2d 1301, 1307 (4th Cir. 1992) ("[W]e fail to see how a state-imposed standard of care relating to product design, manufacture, testing, and the like, can qualify as a labeling requirement under FIFRA."); *In re DuPont-Benlate Litig.*, 859 F. Supp. 619, 623 (D.P.R. 1994) ("[A]llegations that Benlate was defective or inadequately designed can continue to be litigated, while the claim that DuPont failed to warn consumers about the defect or inadequate design is preempted."); *Dow Chem. Co. v. Ebling*, 723 N.E.2d 881, 900-02 (Ind. Ct. App. 2000) (FIFRA does "not preempt strict product liability claims relating to product design, manufacturing or testing as long as they are not based on inadequacy in the product's labeling or packaging."), *vacated on other grounds*, 753 N.E.2d 633 (Ind. 2001).

In any event, the cases prior to *Cipollone* generally held that failure to warn claims (and other claims against pesticide manufacturers) were not preempted under FIFRA, so the law for 20 years after the 1972 Act generally favored *non*-preemption. *See, e.g.*, *Ferebee v. Chevron Chem. Co.*, 736 F.2d 1529, 1541 (D.C. Cir. 1984) (affirming state-law wrongful death verdict against pesticide manufacturer over preemption defense). That was also true of district court decisions. *See, e.g.*, *Montana Pole & Treating Plant v. I.F. Laucks & Co.*, 775 F. Supp. 1339, 1344 (D. Mont. 1991) (denying motion to dismiss because "FIFRA does not impliedly preempt state common law tort claims against manufacturers of EPA-registered pesticides"), *aff'd*, 993 F.2d 676 (9th Cir. 1993) (without discussing FIFRA issue). *See generally* 101 ALR Fed. 887 (1991) (collecting pre-*Cipollone* FIFRA preemption cases); Pet. Br. 42 n.30. Post-*Cipollone* cases have largely ignored *Medtronic*'s more apposite analysis of "requirements" under a statute more analogous to FIFRA than the 1969 Tobacco Act, and upheld preemption under the same type of "requirements" *uber Alles* approach advanced by Dow. *See* Dow Br. 27 n.17.

farmers' claims. *See* C.A. Rec. 264-324 (entitled "Motion for Summary Judgment on Principles of Federal Pre-emption and the Uniform Commercial Code"). As Dow has acknowledged, "no pre-trial discovery was undertaken in this case." Dow Cert. Opp. 3.[15] It would therefore be inappropriate to require the farmers to have produced "evidence" in support of their claims before discovery is permitted. *See Swierkiewicz v. Sorema N.A.*, 534 U.S. 506, 512 (2002).

2. *Express Warranty*. Dow admits (at 44) it went further than merely providing the required directions for use by stating that it "warrants" Strongarm for those uses. As this Court held in *Cipollone*, such voluntary warranties are not preemptive "requirements." Pet. Br. 42-44. The off-label warranty claims based on Dow's representations that Strongarm was "excellent" for use on West Texas peanuts would thus survive even if Dow were correct that they added nothing to the label's express warranty; in addition, such off-label claims are never preempted because they are not made on the "labeling" as required by § 136v(b). *See* § 136(p) (defining "label" and "labeling"); Pet. Br. 44-45.[16]

3. *Fraud/Deceptive Trade Practices*. Dow claims that the Court's *Cipollone* analysis (*see* Pet. Br. 46-47) is inapplicable because § 136v(b) preemption "does not turn on the source of the legal duty," but rather on the effect of the remedy. Dow Br. 46. That assertion cannot be squared with this Court's holding that fraud claims based on statements in advertising were not preempted even though the 1969 Tobacco Act generally preempted "requirement[s]" "with respect to . . . adver-

[15] Dow filed its summary judgment motion based on preemption soon after filing its complaint, and one day after the district court denied the farmers' motion to dismiss for lack of jurisdiction. *See* JA 2.

[16] Dow wrongly asserts that its representations would be considered inactionable "puffing" as a matter of Texas law. *See Helena Chem. Co. v. Wilkins*, 47 S.W.3d 486, 502-04 (Tex. 2001) (rejecting puffery defense and affirming jury verdict on seller's false and misleading claims that grain sorghum seeds would be "excellent" for plaintiff farmers' lands). In any case, neither of the courts below addressed this state-law issue.

tising." *Cipollone*, 505 U.S. at 515. A duty not to mislead does not impose a relevant labeling requirement. And fraud claims based on Dow's off-label statements are clearly not preempted, because § 136v(b) is limited to "labeling or packaging" requirements. As Justice O'Connor's *Medtronic* opinion explained, "[w]here a state cause of action seeks to enforce a [federal] requirement," the federal law "does not preclude States from imposing different or additional *remedies*, but only different or additional *requirements*." 518 U.S. at 513 (concurring in part).

4. *Negligence*. Dow now admits (at 43, 47) that manufacturing defect (both negligent and strict liability) and negligent-testing claims are not preempted. Those concessions compel a remand, as the farmers' claims allege such negligence. *See* Pet. Br. 47-48.[17] Discovery could well establish that Dow simply goofed in testing Strongarm and in mixing the batches of Strongarm sold to the farmers. Dow incorrectly contends (at 47) that the farmers' negligent-testing claims necessarily reduce to a failure to warn. Its argument rests on the same fallacy as Dow's arguments on the strict liability claims: the fact that a different label warning might

[17] Dow's assertion (at 47) that the farmers did not allege a claim that could encompass, for example, "contaminat[ion] in the manufacturing process," is belied by the complaint's allegation of negligence in the "development, testing, *manufacture*, *production* and promotion of Strongarm." JA 185 (emphasis added); *see* Pet. Br. 47. Only discovery can reveal whether the failure of Strongarm is due to a manufacturing defect, because information about Dow's manufacturing operations and processes is in its sole possession – as Dow acknowledged when addressing the manufacturing-defect theory in its summary judgment motion. *See* C.A. Rec. 311 ("If a particular lot number is identified, Dow AgroSciences can produce the retainer samples and demonstrate compliance with all product specifications and the EPA-approved confidential statement of formula."); *id.* at 367-69 (Dow affidavit addressing manufacturing-defect theory). Although this case is before the Court on Dow's summary judgment motion, that motion was based solely on preemption; Dow did *not* move for summary judgment on the merits of the farmers' claims. Thus, the Court "must accept as true all of the factual allegations contained in the complaint." *Swierkiewicz*, 534 U.S. at 508 n.1.

have made the product safe for use as originally designed (or persuaded the farmers not to use it at all) does not change the fact that Dow could have formulated its product differently to make it safe for use in West Texas and in compliance with its label. Dow wrongly contends (at 47) that the "central piece of evidence" for negligent testing was its own 180-degree flip-flop in its supplemental label, and so the negligent testing claim therefore also morphed into a failure-to-warn claim. The farmers were never given the opportunity to develop evidence of their negligent-testing claims. Although Dow's rush to change its label evidences that Strongarm was unsuited for the market in 2000, use of that fact does not transform the farmers' claims into preempted failure-to-warn claims.

III. THE POST-USE CLAIMS ARE NOT PREEMPTED

Dow concedes that the post-sale, off-label claims are not preempted but wrongly claims the farmers "did not challenge the district court's limitation-of-remedies ruling in the court of appeals." Br. 50. In fact, the farmers argued that issue in detail in their Fifth Circuit brief, *see* Pet. C.A. Br. 57-60, and Dow joined issue, *see* Resp. C.A. Br. 57-62. Indeed, an "issue presented" by Dow was whether "certain provisions on the Strongarm label are valid and enforceable limitations on the available remedy for . . . alleged post-application representations." *Id.* at 2; *see also id.* at 6 (summary of argument).

Nothing in FIFRA required Dow to place a limitation-of-remedies provision on the label, and Dow acknowledges here that FIFRA does not preempt these post-use claims. Nor does Dow contest the black-letter rule in Texas that a limitation of liability for fraud is void. *See* Pet. Br. 47 n.34, 49 n.35. Accordingly, the Court should reject Dow's erroneous waiver argument and remand for further proceedings on whether, as a matter of state law, the label's limitation-of-liability provision could immunize Dow's false off-label statements.

CONCLUSION

The court of appeals' judgment should be reversed.

Respectfully submitted,

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